GETINGE

GETINGE GROUP

GETINGE POKA-YOKE AER
A SAFER WAY TO REPROCESS ENDOSCOPES

POKA-YOKE MEANS “ERROR-PROOFING”

As the use of endoscopes increases, so does the frequency of infections linked to endoscope reprocessing.

This is indeed an area where “zero tolerance” towards cross-contamination must be maintained. And at Getinge, we’re convinced that there’s only one way to do this.

Think SYSTEM, not PRODUCT.

And ask yourself: how can our routines ensure that things are always done in the right way? With emphasis on “always”?

The Japanese word poka-yoke stands for a concept aiming to make errors impossible. When we designed our new AER, Automated Endoscope Reprocessor, we applied poka-yoke thinking.

We built it into the product, and into the workflow around the product. We applied a system approach, in the way that we always do at Getinge – the way of thinking that has made us the world leader in disinfection and sterilization.

Let us introduce the Getinge POKA-YOKE AER – a more comprehensive approach to infection control in endoscope reprocessing.

SAFER, FASTER, MORE VERSATIL AND EASIER TO USE

Here's a crash course:

Thanks to the unique lid design, you can have a dirty-to-clean workflow even if your reprocessing room is small. This is important in reducing cross-contamination risks.

Hands-free operation, both on loading and un-loading sides, means that you don't have to touch any panels or buttons with dirty hands. Open the AER with the foot pedal, let the RFID choose the right cycle and the AER starts automatically.

Unique handling of chemicals. The Aperlan Poka-Yoke disinfectant bottles can only be placed in one way – the right one. The machine will also pierce and inject them, so there's no operator exposure whatsoever.

Optimum traceability is built-in. Thanks to RFID tags, info on operators and endoscopes is automatically stored and printed along with the cycle data.

The cycles are fast and efficient for all flexible endoscopes. In fact, no other AER can run such an extensive program in just 22 minutes*, conforming to national and international regulations, so quickly.

To secure maximum infection control, one must consider the whole workflow. That's why we offer not only an endoscope reprocessor, but a complete reprocessing system.

**26 minutes when a second wash is needed (France)*

MODERN INFECTION CONTROL – THERE'S ALWAYS TWO SIDES TO IT

DIRTY SIDE

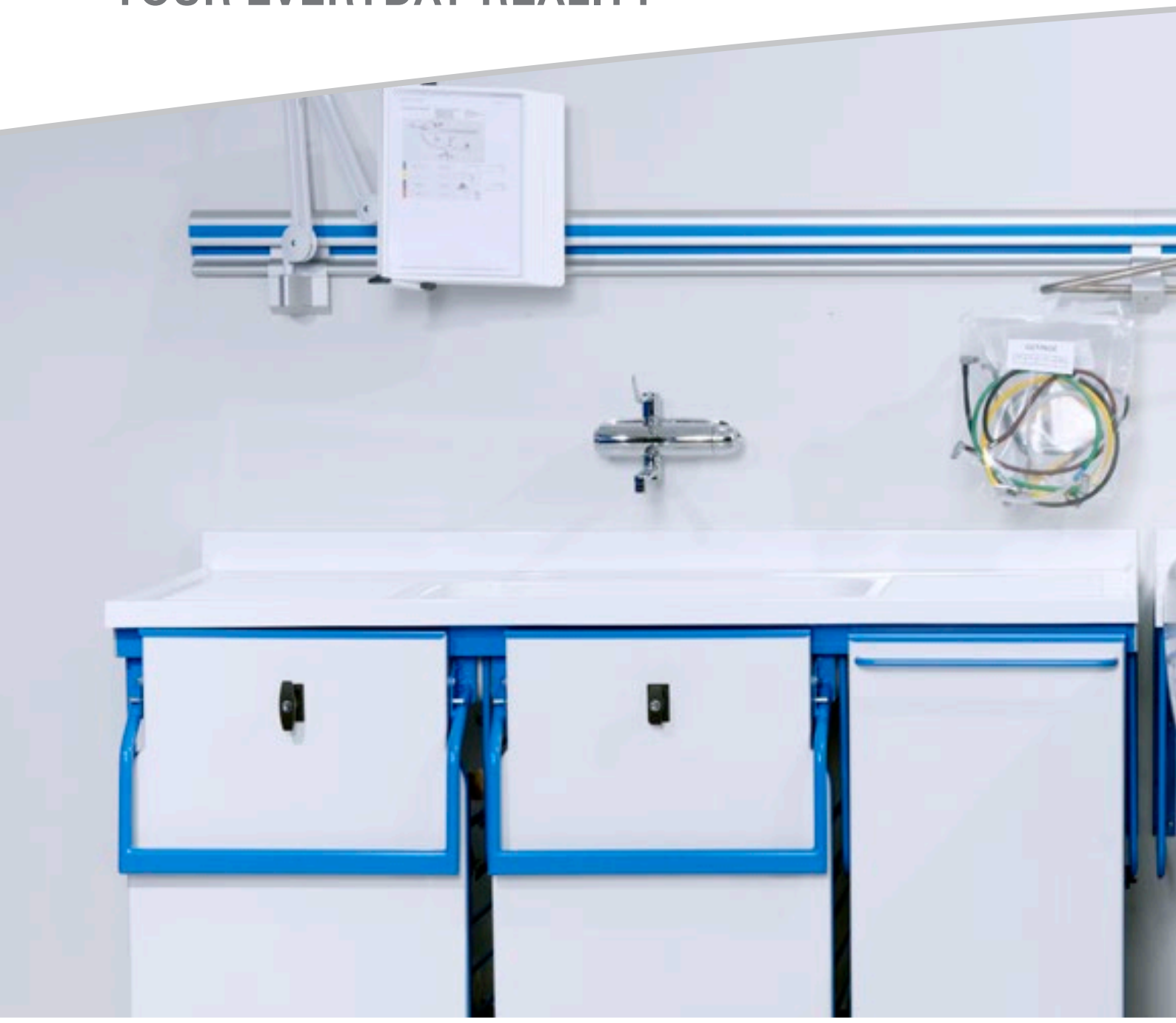
Modern infection control is based on the barrier principle, a clear separation of dirty and clean areas. The POKA-YOKE AER solves the problem by featuring a lid that allows loading and unloading from opposite sides.

Manual pre-treatment is performed on the dirty side. In this way, disinfected endoscopes never have to be handled in the same area as dirty ones.

The design of the POKA-YOKE AER creates a barrier between dirty and clean areas, reducing the risk of cross-contamination.

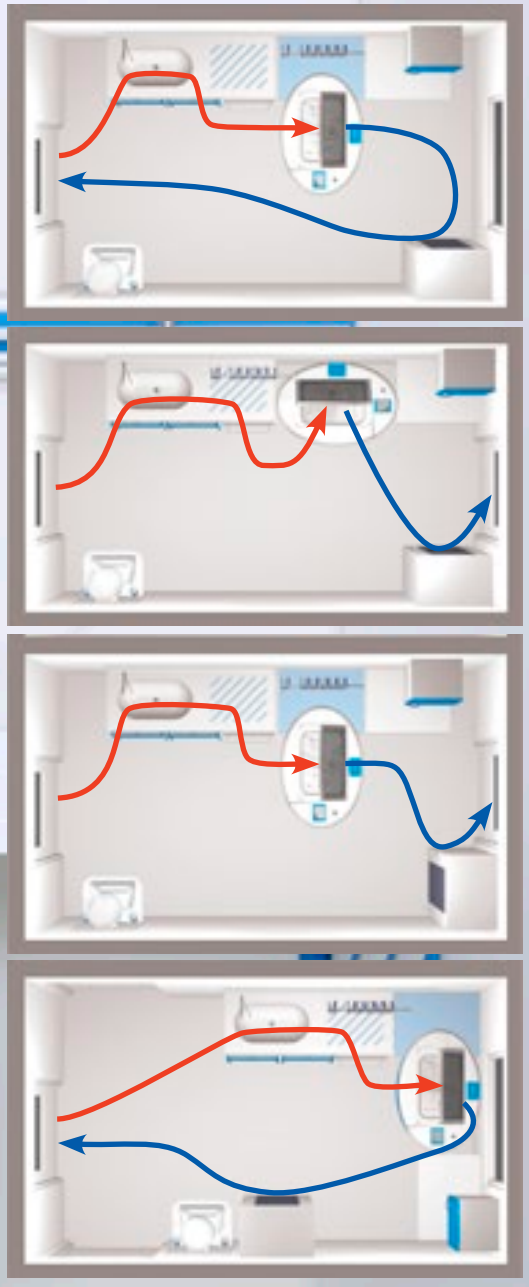
On the next page, you'll see an example of how the POKA-YOKE AER functions as the core of a complete hygienic system, ensuring maximum hygiene safety even where space is limited.

A SYSTEM APPROACH BASED ON YOUR EVERYDAY REALITY



Getinge POKA-YOKE AER is the ideal solution for smaller endoscopy clinics. Here, there is often not enough space to build a machine into a wall in order to separate dirty and clean areas. Thanks to the smart lid, opening to the opposite side for unloading, the Getinge POKA-YOKE AER allows a soiled-to-clean workflow even in a small room.

Manual pre-treatment in a dedicated part of the room
After the initial manual cleaning and flushing of channels has been performed in the procedure room, the endoscope is brought into the reprocessing room. Here, there is a dedicated area for continued manual cleaning on one side of the Getinge POKA-YOKE. Equipment in this area includes sinks, spray guns, automated water tap, preparation area, shelf for brushes, waste bin etc.



There are various ways of positioning the POKA-YOKE AER in the reprocessing room.

The AER as a semi-divider of the room

Ideally, the AER is placed away from the wall, by a special wall-mounted work bench to function as a semi-divider in the room. However, there are several options for positioning it, that enable a hygienic workflow – see examples on the right. Shelves for endoscope connectors and adaptors and a stand for a flipchart are examples of accessories that are conveniently close to the AER.

Drying and storage on the clean side

When the reprocessing cycle is completed, the endoscope is unloaded on the clean side.

In this area you need a storage cabinet for sterile goods, a printer for process data, a wall-mounted work bench for final assembly of the endoscope, and an endoscope storagecabinet. For details on all accessories, see the following pages.

LOAD, START AND UNLOAD WITHOUT TOUCHING

Infection control is about seeing the whole picture, and as far as possible, ensuring the risk of human errors is eliminated.

For example: avoiding the situation where a nurse touches a handle, panel, start-button or barcode reader after holding a dirty endoscope, leaving micro-organisms waiting to be picked up when unloading the clean endoscope?

The answer is: touch-free operation.

The first part is basic: a foot pedal

After the manual pre-cleaning, the operator presses the pedal to open the AER. No need to touch any handles or buttons.

After successful decontamination the door can only be opened with the pedal on the clean side.

Then, the best part: RFID identification and automatic start

When the operator has placed the endoscope into the AER, its RFID tag is automatically identified by the machine's RFID antenna (RFID = Radio-Frequency Identification). The operator also has a RFID tag for automatic user identification.

When the foot pedal is pressed, the Getinge POKA-YOKE will close the lid and automatically starts endoscope reprocessing.

Smooth, simple and failsafe

This procedure has several benefits. Firstly, it is easy and saves time for the operator. No data to be entered, just load the endoscope and press the pedal.

Secondly, it reduces the risk of human errors. Only the correct cycle for that particular endoscope can be used. The AER cannot be started or unloaded without storing the correct user information.

Thirdly, it reduces the risk of cross-contamination. No buttons to touch to open or close the lid, select a cycle, enter user information, start the AER or unload the clean endoscope.

It couldn't be simpler – or safer.

KEEP YOUR
HANDS OFF

DATA CAPTURING AND TOTAL TRACEABILITY – TAKE COMMAND OF YOUR ENDOSCOPES

Automatic data collection with RFID tags
Using RFID tags, both endoscope and operator are automatically identified, so the correct ID information is collected. The AER control system records cycle number, date, endoscope ID, type of cycle, user ID, cycle start and stop time.

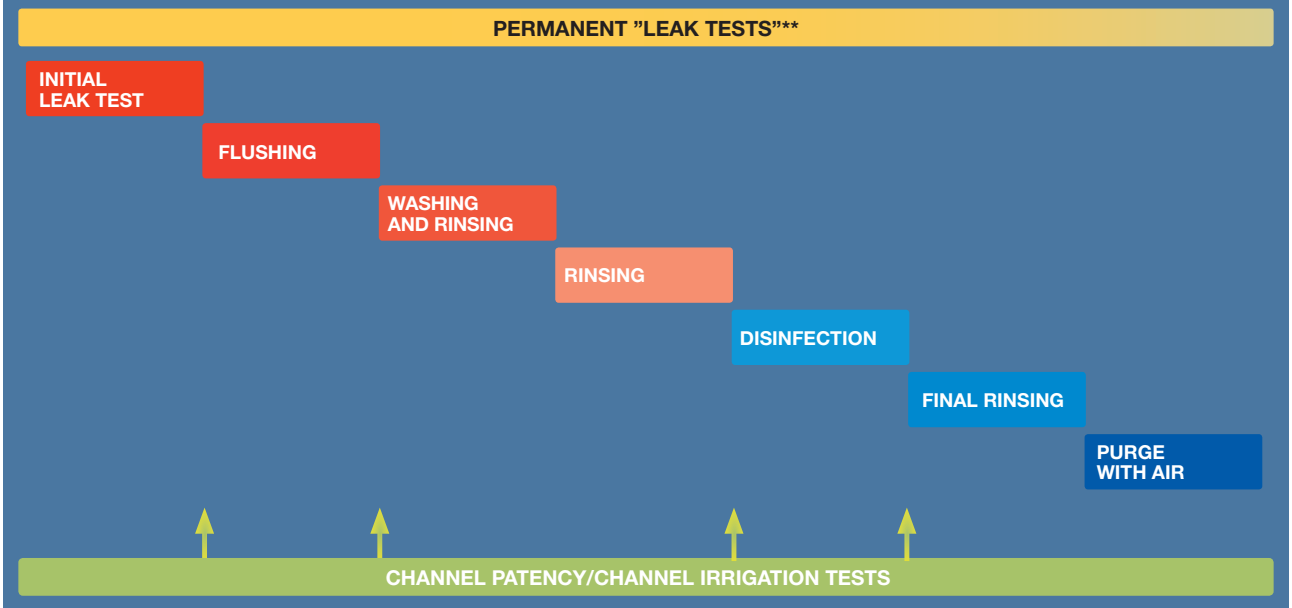
AN EXTENSIVE PROGRAM COMPLETED IN ONLY 22 MINUTES*

The standard program for the Getinge AERs features continuous ”leak tests”**, four flow tests and three final rinses. It’s been designed to meet all regulations, including the ones in countries where demands have increased following the emergence of prion diseases.

No other machine can complete so many phases in such a short time. As a result, the Getinge AERs will complete a cycle, fully validated, in accordance with the EN ISO 15883-1 and EN ISO 15883-4 standards in only 22 minutes*.

On top of this, you can save time thanks to the smart ergonomic design of the AERs. Loading scopes is very easy, and connecting them is really fast. All the time you have a good overview of the chamber, which contributes further to a smooth and simple workflow.

STANDARD CYCLE DESCRIPTION



Initial flush phase
Removes any pretreat-ment chemical and removes gross contamination.

Wash phase
Ensures that all proteins are removed. Optional 2nd washing and rinsing phase can be programmed.

Extensive rinses
Every wash phase is followed by a rinse, plus an extra one – for complete removal of detergent before disinfection.

Disinfection phase
The standard program features a 5 minutes minimum contact time, perfor-med at 37°C.

Triple rinses
The final rinse uses 0.1 µm filtered water to guarantee the disinfected status of the endoscope.

Special program for clean endoscopes – saves time
A shorter 14 minutes disinfection cycle is available for processed endoscopes that have been stored too long to use without renewed reprocessing. To be used according to local regulations.

Programmable thermal self-disinfection program
The self-disinfection program uses thermal disinfection to reduce risk of contamination. By pre-setting the program for automatic start, you know that the AER is ready for use, for example in the morning when you arrive.

** 26 minutes when a second wash phase is required (France)*

*** Should the endoscope passes the automatic initial leak test, a continuous air overpressure is maintained to protect the endoscope’s internal components*

UNIQUE EXTRA SAFETY THANKS TO THE CHANNEL IRRIGATION SYSTEM

Endoscopes are not like other medical instruments. Disinfecting them is more complicated due to the complexity of the different internal channels.

How do you assure that these channels – the inside of which no one will ever see – have been completely high-level disinfected and are 100% safe to use on the next patient after each reprocessing cycle?

How can you be completely sure that each channel is 100% functional and that there is no obstruction due to bio-film build-up threatening the scope's perfomance?

There is only one way. The unique CVL system (Channel irrigation Verification Library), which measures each channel separately, and warns if there is the slightest deviation compared to predefined values.

This is something that other AERs do not offer. And it is priceless for those who appreciate peace of mind when it comes to patient safety.

It works like this:

1. The AER compares* the measured pressure to pre-defined values that have been determined through our partnership with the main manufacturers of endoscopes – in order to assure that the cleaning and disinfection of each channel is correctly performed.
2. During operation, the AER automatically compares the flow of each channel of each endoscope with the known reference values. If there is a deviation in the flow rate during the cycle, the AER notices it and warns the user by means of an alarm message.

This way, you know that continuous safety is always assured.
The CVL functions as a quality assurance, letting you feel confident that everything works as it should on a day-to-day basis.

Normal pressure
Everything works correctly and the flow is normal.

High pressure – CVL warns
The pressure is high but the flow through the channel is very low. Possible cause: obstruction (due to bio-film build-up or damage).

Low pressure – CVL warns
The pressure is very low, still the water and chemicals seems to flow totally unhindered. Possible cause: the endoscope is not connected.

As decontamination in an AER is a terminal/final process prior to use on a patient, you have to be absolutely sure that the disinfection has been 100% successful. Thanks to the CVL system, you can rest assured.

** CVL availability is dependent on the endoscope design*

EASY TO USE WITH ALL* ENDOSCOPES – CONNECTOR DATABASE ON THE WEB

The Getinge Infection Control Group knows a thing or two about safe reprocessing. Being the world leader in disinfection and sterilisation, it is even tempting to claim that we know more about it than anyone.

So both you and the manufacturer of your endoscopes can rest assured – whatever the type or brand, a Getinge AER is tested to provide full compatibility and efficacy.

Extensive testing of different endoscopes

Getinge POKA-YOKE AER is developed for and extensively tested with different types and brands of flexible endoscopes. They handle scopes for, amongst others, upper and lower GI endoscopy, cystoscopy**, hysteroscopy**, bronchoscopy and rhinolaringoscopy.

Easy to connect any type of endoscopes previously identified

The Getinge AERs identify the endoscope and display help for the operator on the screen. Also each tube for the connection of internal channels has a different colour to ease the connection. Customised and skillfully engineered endoscope connection kits are available for usual endoscope models.

** May vary from country to country.*
*** Tested according to local regulations.*

A SAFER WAY TO HANDLE DETERGENTS – NO EXPOSURE AT ALL

We made our AER extra easy to use in everyday work. And we've also simplified changing detergent and disinfectant containers.

We have made it easier – and much safer. We made it impossible to make errors – and minimised any exposure to chemicals.

High-efficiency detergent

Getinge POKA-YOKE AER use the detergent Getinge Poka-Yoke DLC, which is an alkaline type detergent with well-documented efficiency for protein and biofilm removal. The 3 litre containers last for 60 cycles.

APERLAN for best disinfection efficacy

The disinfectant used by Getinge POKA-YOKE AER is the peracetic acid-based Aperlan Poka-Yoke, delivered in two separate 5 kg containers – Agent A and Agent B. The two agents are mixed inside of the machine and last for about 80 cycles. Aperlan Poka-Yoke Agent A & Agent B is used as single shot, i.e. it is not recycled/reused

Disinfectant containers can only be placed in one way – the right way

Since the bottles of Agent A and B have different shapes, they can only be positioned in the place allocated for them. No room for human errors.

The containers do not have to be opened

The bottles of Agent A and B are pierced inside the AER. This means that the operator will not be exposed to any possible health-hazardous chemicals. Safer for the operator and no chemical fumes in the reprocessing room.

Warning when container levels are low

The level of detergent and disinfectant is constantly monitored by the control system and can be displayed on the operator screen. The system warns if levels are low – no risk of running out of chemicals during a cycle.

The AER feature a built-in storage space for the detergent and the disinfectant containers.

The large double door makes it easy to access the containers and replace them.

GETINGE

ACCESSORIES FOR A FULLY EQUIPPED REPROCESSING ROOM

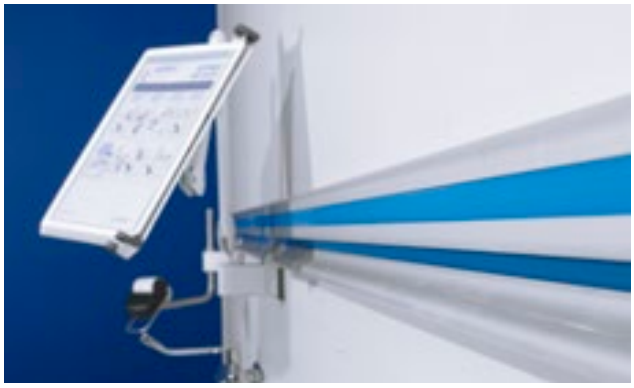
Getinge offers everything you need to ensure the best possible hygienic workflow in your reprocessing room. Here are examples of the accessories available. For more information and layout suggestions for your reprocessing room, please visit www.getingepokayoke.com.

1. Pre-treatment unit
For manual pre-treatment of endoscopes before the process. Made of gentle composite material.

2. Chemical storage trolley
For storage of 2+2 disinfectant bottles and 3 DLC-detergent bottles. The trolley is also lockable to the pre-treatment unit for safe storage.

3. Waste trolley
For general waste such as gloves, brushes etc, this trolley is positioned under the pre-treatment unit for easy access. Foot-pedal opening.

4. U-shaped transfer table
Serves as a barrier between the dirty and clean sides. It has the same shape as the POKA-YOKE AER and is made of gentle composite material.



5. Wall rail
Made of sturdy extruded aluminium, the wall-rail serves as a multi-purpose holder. Can be used to hold/conceal wiring, cords etc.

6. Chart holder
Mounted on the wall-rail, the swivel chart holder keeps instructions for use/manual pre-cleaning etc close at hand.

7. Connector holder system
Also mounted on the wall-rail, the connector holder transfers clean connectors back to the dirty side for storage and re-use. The connectors are safely and hygienically transfered in a practical disposable plastic bag.

8. Printer holder
The printer holder gives easy access to print-outs once the process is finished. Mounted on the wall-rail.

9. Clean table
The clean table serves as a worktop for assembly of processed flexible endoscopes. Made of gentle composite material.

EASY INSTALLATION AND COST-SAVING SERVICE SOLUTIONS

The Getinge POKA-YOKE AER is designed to be very easy to install and service. Putting it in place and connecting to water, drain and electricity is quick and easy.

Choice of unloading mode can be made at installation, by selection in the software for either same-side unloading or opposite side unloading. This setting can also be easily changed later, for example if a new reprocessing room layout will allow the dirty-to-clean workflow that wasn't possible at installation.

All the training support you may need

We offer* operator training to ensure that the Getinge POKA-YOKE can be optimally utilized to its full potential. To prevent breakdowns and minimize the risk for undesired downtime, there is also training available for your technician at the unit. Please contact your local representatives to have more information about trainings.

The trainning session can be held at your facility or at the Lancer/ Getinge Academy.

Preventive maintenance and validation* packages

We also offer* a range of preventive maintenance service contracts as well as validation and training packages which can be tailored to your own requirements:

- Installation to agreed services
- Commissioning
- Installation & Operational Testing (IOT) validation to the EN ISO 15883-1 and EN ISO 15883-4 standards
- Performance Qualification (PQ) validation testing to the EN ISO 15883-1 and EN ISO 15883-4 standards
- Servicing and service contracts
- Routine test to the EN ISO 15883-1 and EN ISO 15883-4 standards

**availability of the services to be checked locally*

CONFORMS TO ALL* NORMS AND STANDARDS – AND THOROUGHLY TESTED IN EVERY WAY

Our centre of excellence for endoscope reprocessing in Toulouse, France.

Manufactured to the highest standards

Thorough experience and well-established expertise are prerequisites for reliable production of AERs. The Getinge POKA-YOKE is manufactured at our centre of excellence for endoscope reprocessing in Toulouse, France. This site has been manufacturing AERs as well as related accessories and equipment since 1993. A new assembly line for the AERs has been built according to lean manufacturing principles.

Proven, scientifically tested technology

The Getinge AERs include proven, scientifically tested technology on endoscope channel irrigation systems/ alarms, regulation and monitoring of cycle parameters, chemical combination efficacy/compatibility – and much more.

Getinge POKA-YOKE AER conforms to the following norms amongst others:

- European Machine directive 2006/42/EC and Medical Device directives 93/42/EEC
- EN ISO 15883-1 standards
- EN ISO 15883-4 standards
- Guide CTIN 11/2003 (France)

Endoscope compatibility testing

An independent laboratory (endocopy specialist) conducted an extensive testing of endoscope compatibility, where endoscope materials and parts were exposed to the maximum dosing of disinfectant possible in the Getinge AERs and showed no deterioration.

Endoscope connection

We have developped** the appropriate connection kits for the main endoscopes of the major manufacturers. Our kit are certified MEDICAL DEVICE CLASS I.

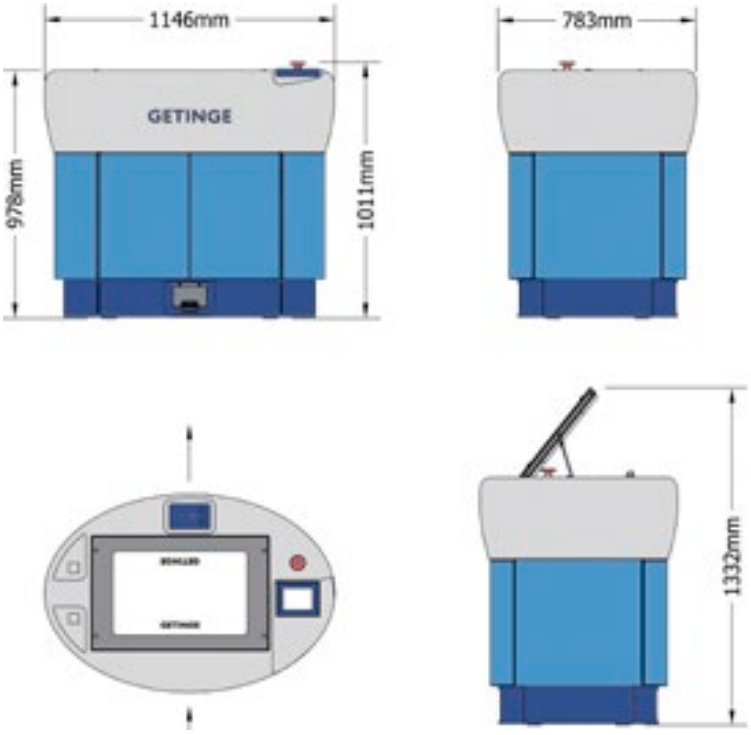
Scientific efficacy testing

These tests were also performed by an independent laboratory. The tests included:

- Biocidal activity of the Aperlan Poka-Yoke
- Bactericidal, fungicidal, mycobactericidal, virucidal, sporicidal according to EN or ISO standards on disinfectants
- Bactericidal and sporicidal activity of the disinfectant according to EN ISO 15883-4 standards
- Cleaning efficacy tests according to ISO 15883-4
- Endoscope disinfection cycle efficacy tests according to EN ISO 15883-4 standards
- Self disinfection cycle efficacy tests according to EN ISO 15883-4 standards (including water treatment unit)

** Applies to EN ISO 15883-1 & 15883-4, please check conformity to local requirements.*
*** Please contact your local Getinge representative to check availability of the required kit.*

TECHNICAL DATA



GETINGE POKA-YOKE AER:

GENERAL FEATURES:

Number of endoscopes:	1
Blue-tinted glass lid, can open to both sides	✓
Full compliance with EN ISO 15883-1	✓
Full compliance with EN ISO 15883-4	✓

SPRAYING- & CVL SYSTEM

4 rotating nozzles 360°	✓
6 internal channel connections, colour coded	✓
CVL system	✓

MACHINE DISINFECTION

Thermal disinfection cycle	✓
Chemical self-disinfection	✓

ENDOSCOPE DISINFECTION CYCLES

Permanent "leak tests" *	✓
Max number of channel irrigation tests during full cycle	4
Working temperature	37°C
Automatic mixing of disinfectant inside machine	✓
Standard time of contact with disinfectant	5 min
Adjustable final air blowing time	✓

CONSUMABLES

Disinfectant Aperlan Poka-Yoke, Agent A	5 kg box of 2 containers
Aperlan Poka-Yoke, Agent B	5 kg box of 2 containers
Detergent Getinge Poka-Yoke DLC	3 litres box of 4 containers

CONNECTION OF UTILITIES

Electrical connections/consumption	230V -1ph +/-10% 26A/ph
	400V 3ph+n +/-10% 8A/ph
Water supply	To national guidelines and requirements. Minimum softened water <7 DH.
Incoming water filter 0,1 µm	✓
Water consumption per cycle**:	26 L
HEPA filter for incoming air	✓
Net weight	150 kgs

CONTROL/VALIDATION/TRACEABILITY

Industrial PLC system (Programmable Logic Controller)	✓
Printer	✓
Program for identification of endoscopes and CVL identification	✓
RFID identification of endoscope	✓
RFID identification of user	✓
Automatic dosing of detergent	✓
Automatic dosing of disinfectant	✓
Independent cycle parameters monitoring system	✓
Cycle documentation system	✓
Ethernet, IP address for Remote	✓

INCLUDED FOC ON DELIVERY

Endoscope RFID-tags	3 pcs
User RFID-tags	2 pcs
Machine disinfection-tag Ao 600	✓
Machine disinfection-tag Ao 3000	✓
Machine disinfection chemical	✓
User manual	✓

** Should the endoscope passes the automatic initial leak test, a continuous air overpressure is maintained to protect the endoscope's internal components.*
*** standard cycle with one wash phase.*

Getinge Infection Control is the world leading provider of solutions for sterile processing in the healthcare sector. We aim to ensure the highest quality and safety at the lowest total cost. We offer complete solutions for a seamless work-flow, reducing the risk of contamination while helping healthcare to increase efficiency.

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GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. **ArjoHuntleigh** focuses on patient mobility and wound management solutions. **GETINGE** provides solutions for infection control within healthcare and contamination prevention within life sciences. **MAQUET** specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

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